Pharmaceutical & Medical Device Regulatory Update
Issue 17 | October 2014
JONES DAY

Firm News

Jones Day has added two Life Sciences attorneys to its Brussels, Belgium Office. **Cristiana Spontoni** is a well-known life sciences practitioner, advising in a broad range of areas, including biotechnology, pharmaceuticals, and medical devices on a cross-European basis. **Katherine Llewellyn** is qualified as a UK solicitor and also holds a degree in genetics, bringing a rare and valuable dual background in law and science to the team.

Top News

FDA to Study Effects of Pill Aesthetics on Patient Compliance
FDA intends to survey pharmacists and patients to find out whether the shape, size, or color of a pill influences adherence to the prescribed dosing regimen. FDA previously issued a draft guidance recommending generic manufacturers make their pills look similar to the brand name drug, indicating its interest in how aesthetic changes in pill appearance are linked to health outcomes.
Read more below

Health IT Groups Ask Congress for "Statutory Clarity"
About 60 health information technology ("health IT") industry groups recently joined to ask Congress to provide more clarity in health IT laws by codifying a risk-based regulatory framework proposed in April 2014 by FDA, the Office of the National Coordinator for Health Information Technology, and the Federal Communications Commission. The framework was

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UPCOMING EVENTS

Oct. 28: **Laurie Clarke** will speak in Berlin, Germany, on medical device labeling and compliance & UDI implementation.

Nov. 12: **Colleen Heisey** will moderate an ABA Health Law Section webinar on off-label marketing and free speech, focusing on the impact of *Caronia*.

Nov. 13: **Alexis Gilroy** will speak in New York City on telehealth issues at a dermatology course at Memorial Sloan

prompted by the 2012 FDA Safety and Innovation Act, which required the three agencies to collaborate on a regulatory scheme that would promote innovation while protecting patients. The framework attempts to balance device function against risks to the patient, regardless of the particular technology platform. In their letter, the health IT groups told Congress they want "statutory clarity and a stable foundation for continued innovation in health IT." Other health IT groups have cautioned that the framework is not ready for adoption, urging FDA to issue guidance to clarify several complex issues, such as the scope of medical device accessories and the difference between wellness and disease.

Kettering Cancer Center.

Nov. 13–14: **Christian Fulda** will speak in Brussels, Belgium on European and U.S. transparency standards at the FDLI Conference.

November 20: **Laurie Clarke** will speak at an ABA Health Section webinar on medical device fundamentals.

RELATED PRACTICES

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FDA Takes Action Against Ebola Scammers

Since August 2014, FDA has warned consumers to beware of products sold online claiming to prevent or treat the Ebola virus. FDA's actions are part of the agency's broader effort to stop false claims from spreading quickly through social media by holding the sellers responsible. "Whenever there is some kind of a public health scare, there is some enterprising company that says, 'Oh, I'll create a product and I'll say that it treats that health concern.' And they will sometimes choose to call it a dietary supplement because they think that will evade the attention of the regulators," said Steve Mister, president and chief executive officer for the Council for Responsible Nutrition, a trade group representing dietary supplement manufacturers. In the last month, FDA has sent several warning letters to distributors of essential oils and other products that claim these products prevent or treat Ebola and other ailments. The Federal Trade Commission is also monitoring the internet for these types of claims, says Rich Cleland of that agency's advertising practices division.

FDA Alters Guidance on Reporting for Medical Device Recalls versus Enhancement

In response to requests from manufacturers, FDA deleted a controversial section from the *Guidance for Industry: Distinguishing Medical Device Recalls from Medical Device Enhancements*, no longer requiring an 806 report for device enhancements. The draft guidance issued last year caused the medical device industry to voice its concerns about product liability suits and paperwork burdens if FDA required reporting of any enhancement intended to reduce health risks. The requirement as proposed would also have included reporting for unsold products the manufacturer upgrades as part of an enhancement. FDA removed several reporting requirements from the guidance, prompting a change in the title of the guidance, saying it revised the guidance document "to enhance clarity through the inclusion of multiple new examples." FDA also added a new sentence, clarifying that "changes to improve a nonviolative device's safety or performance" can fall in the category of product enhancements. On November 5, 2014, the FDA will hold a webinar to explain the guidance and to provide a forum for asking questions.

European Trade Group Disfavors Sponsorship of Health Care Professionals at Conferences

The Executive Committee of the European Diagnostics Manufacturers Association ("EDMA") and the Board of the European Medical Technology Industry Association ("Eucomed"), both members of MedTech Europe, announced their recommendation to members to phase out direct industry sponsorship of health care professionals to third-party organized conferences by January 1, 2018. These recommendations are among measures aimed at reinforcing the EDMA and Eucomed Codes of Ethical Business Practice, which will ultimately be known jointly as the MedTech Europe Code of Ethical Business Practice and to which all EDMA and Eucomed members will be bound. This development illustrates the medical device industry's focus on high ethical standards for industry–health care professional relationships.

Other News
FDA Approves Testing for New Ebola Drug

FDA Strengthens Ties with Mexico

Maine Allows Foreign Drug Imports

Documents Leaked in Trans-Pacific Partnership Negotiations Over Drug Patents

EU Commissioner Coggi Resigns

FDA Finalizes Stance on Fixed-Dose Drug Approvals

EU Expands Drug Side Effect Database

UK Creates One-Stop Shop for Regenerative Medications

FDA Announces Efforts to Expedite Medical Device Approvals

More Older Adults Struggling with Substance Abuse

Regulatory Updates

FDA Requests Comments on PDUFA Patient-Focused Development
In the October 8, 2014, *Federal Register*, FDA called for comments on its preliminary list of disease areas for study under FDA's patient-focused drug development initiative under the Prescription Drug User Fee Act ("PDUFA"). ***Comments due December 5, 2014***.

FDA Publishes Modifications to Consensus Standards for Medical Devices
In the October 17, 2014, *Federal Register*, FDA announced certain additions, withdrawals, corrections, and revisions of consensus standards the Agency will recognize for use in premarket submissions and other requirements for devices. These modifications will be incorporated in the list of FDA Recognized Consensus Standards in the Agency's searchable database.

FDA Determines LUPRON DEPOT Not Withdrawn for Safety or Effectiveness Reasons
In the October 8, 2014, *Federal Register*, FDA published its determination that LUPRON DEPOT (leuprolide acetate for depot suspension), an injectable vial containing 3.75 milligrams of the drug, was not withdrawn from sale for reasons of safety or effectiveness.

FDA Issued the Following Draft and Final Guidance Documents
Draft Guidance for Industry: Two-Phased Chemistry, Manufacturing, and Controls Technical Sections. October 20, 2014, *Federal Register*. ***Comments due December 19, 2014***.

Guidance for Industry: New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products. October 16, 2014, *Federal Register*.

Guidance for Industry and FDA Staff: Distinguishing Medical Device Recalls from Medical Device Enhancements. October 15, 2014, *Federal Register*.

Draft Guidance for Industry and FDA Staff: Flow Cytometric Devices. October 14, 2014, *Federal Register*. ***Comments due January 12, 2015***.

Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms. October 9, 2014, *Federal Register*.

Draft Guidance for Industry: Critical Path Innovation Meetings. October 10, 2014, *Federal*

Register. ***Comments due December 8, 2014***.

Guidance for Industry: Pathological Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval. October 6, 2014, *Federal Register*.

Draft Guidance for Industry: The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements; Questions and Answers. October 7, 2014, *Federal Register*. ***Comments due December 8, 2014***.

Draft Guidance for Industry: Over-the-Counter Pediatric Liquid Drug Products Containing Acetaminophen. October 7, 2014, *Federal Register*. ***Comments due December 8, 2014***.

Information Collection Activities

FDA Announced that OMB Has Approved the Following Collections

- General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions
- Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded
- Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products

FDA Announced the Following Collections Have Been Submitted to OMB for Approval

- Medical Device Tracking
- Animal Drug User Fee Cover Sheet
- Orphan Drugs; Common European Medicines Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation

FDA Announced the Following Proposed Information Collections

- Labeling of Natural Rubber Latex Condoms
- CGMP for Blood and Blood Components: Donor Testing and Notification
- Survey of Pharmacists and Patients: Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions
- Exports: Notification and Recordkeeping Requirements

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics

Public Workshop on Innovations in Breast Cancer Drug Development—Next Generation Oncology Trials, Breast Cancer Workshop will be held on **October 21, 2014**, in Bethesda, MD.

Public Meeting and Scientific Workshop on the topic of Female Sexual Interest/Arousal Disorder will be held **October 27–28, 2014**, in Silver Spring, MD.

The First Annual Neonatal Scientific Workshop—Roadmap for Applying Regulatory Science to Neonates will be held on **October 28 and 29, 2014**, in Silver Spring, MD.

Public Meeting on Development and Regulation of Abuse-Deterrent Opioid Medications will be held **October 30–31, 2014**, in Silver Spring, MD.

Training Course for Clinical Investigators on Scientific, Ethical, and Regulatory Aspects of Clinical Trials will be held **November 4–6, 2014**, in College Park, MD.

A Public Workshop on FDA's Clinical Trial Requirements for Research Professionals will be held **November 5–6, 2014**, in Lake Buena Vista, FL.

FDA Industry Meeting: Electronic Postmarket Safety Reporting Updates will be held October 27, 2014, in Silver Spring, MD.

Medical Devices
Public Workshop on Collaborative Approaches for Medical Device and Healthcare Cybersecurity will be held **October 21–22, 2014**, in Arlington, VA.

Training Course for Clinical Investigators on Scientific, Ethical, and Regulatory Aspects of Clinical Trials will be held **November 4–6, 2014**, in College Park, MD.

Public Workshop on Regulatory Science Considerations for Software Used in Diabetes Management will be held **November 13, 2014**, in Silver Spring, MD.

Public Workshop on Brain–Computer Interface Devices for Patients With Paralysis and Amputation will be held **November 21, 2014**, in Silver Spring, MD.

Advisory Committees
October 30, 2014: Cardiovascular and Renal Drugs Advisory Committee (to discuss NDA for the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation)

November 6, 2014: Cellular, Tissue, and Gene Therapies Advisory Committee (to discuss *Draft Guidance for Industry: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products* and the Dear Gene Therapy IND or Master File Sponsor Letter)

November 6, 2014: Oncologic Drugs Advisory Committee (to discuss an NDA for a drug used in combination with other drugs to treat multiple myeloma)

November 6–7, 2014: Science Advisory Board to the National Center for Toxicological Research Advisory Committee (to provide a centerwide update and present research needs)

November 14, 2014: Ophthalmic Devices Panel of the Medical Devices Advisory Committee (to discuss premarket approval of an interocular lens implant)

November 18, 2014: Drug Safety and Risk Management Advisory Committee (to discuss risk evaluation and mitigation strategies and elements to assure safe use of eculizumab (SOLIRIS))

November 19, 2014: Science Board to the FDA (to discuss data related to anesthetics and sedation drugs in children)

November 24–25, 2014: Anesthetic and Analgesic Drug Products Advisory Committee (to discuss the risks–benefit balance of epidural steroid injections for inflammation and pain management)

December 12, 2014: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee (to discuss premarket approval of a spine-spacing device

For more comprehensive listings of FDA meetings, please visit these FDA web pages:
Meetings, Conferences, and Workshops (Drugs)

Workshops, Meetings, and Conferences (Biologics)

Workshops and Conferences (Medical Devices)

FDA Advisory Committee Calendar

Recent Drug and Device Approvals/Clearances

FDA Approves Labels with Abuse-Deterrent Features for Extended-Release Opioid Analgesic (Oct. 17, 2014).

FDA approves Ofev to treat idiopathic pulmonary fibrosis (October 15, 2014)

FDA approves Esbriet to treat idiopathic pulmonary fibrosis (October 15, 2014)

FDA permits marketing of urinary prosthesis device for women (October 14, 2014)

FDA approves a new ultrasound imaging agent (October 10, 2014)

FDA approves first combination pill to treat hepatitis C (October 10, 2014)

FDA approves first drug-coated angioplasty balloon catheter to treat vascular disease (October 10, 2014)

FDA approves Akynzeo for nausea and vomiting associated with cancer chemotherapy (October 10, 2014)

For additional information on drug and device approvals and clearances, please visit FDA's web pages on Drug Approvals and Databases (includes biologics) and Device Approvals, Denials, and Clearances.

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About 85 percent of all medications prescribed in the U.S. are generic drugs, and because generics are often treated interchangeably, the appearance of a patient's medication may change depending on the generic supplier.

According to the FDA information collection notice, "[s]tudies indicate that patients are more likely to stop taking their generic medications when they experience a change in their drugs' physical characteristics, leading to harmful clinical and public health consequences, as well as increased health care costs." FDA says it will ask pharmacists how often generic suppliers change and whether they employ strategies to help patients transition between pills with a different appearance. FDA will also poll patients, focusing on older adults with epilepsy, diabetes, hypertension, hyperlipidemia, depression, HIV, or combinations of these six conditions.

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